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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/815,888 | 03/31/2004 | Nam T. Chao | DUQ-001 (DEP5289) | 9089 |
| 959 | 7590 | 07/03/2006 | EXAMINER | |
| LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109 | | | PREBILIC, PAUL B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/815,888

Applicant(s)

CHAO ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-14 is/are allowed.
- 6) ☒ Claim(s) 1-10 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on April 11, 2006 is acknowledged. The traversal is on the ground(s) that the proposed use by the Examiner ignores the purpose and functionality for the invention as claimed. This is not found persuasive because the method described by the Examiner is considered an acceptable alternative method in that the functional language does not limit the structure to a device to that extent. Furthermore, the device as claimed could be used in a nail engaging procedure or to engage any implant that is not a screw such as is encompassed by claim 1.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15 to 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 11, 2006.

This application contains claims 15-20 drawn to an invention nonelected with traverse in the response filed April 11, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 & 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker (US Pat# 2248054). Becker discloses an engagement mechanism (7) of claws and a shaft (19) movable relative to the first engagement mechanism, with a second engagement mechanism (20) of a blade for selectively engaging the implant screw , which when the two mechanisms are engaged will rigidify the implant from its loose state (Figure 1) to a secured rigidified state (Figure 5) via a distraction between the first portion and second portion, where the first engagement mechanism (20) is pushing the implant, and the second engagement mechanism (7) is pulling the implant. The device comprises a body (6) defining an axially extending passage (5) for the spindle shaft (12), where the shaft (12) is within the body/handle (6) and shank (5), which also is a rotatable collar, which when rotated in one direction, relative to the head (13) will cause the shaft to push out the blade portion (20), and when rotated in the other direction will retract the blade. The device includes a transverse screw/pin (14, 24) with a pin projection (15, 25) with a threaded surface for engagement along the insertion slot of the screw/pin (24), which will limit the axial movement of the pin and shaft when fully engaged. The instrument includes alignment protrusions formed on the tip, being a cupped end (26, 27) and the claw (7) protrusions and bias spring (21, column 2, lines 21-29).

Claims 1-4, 7 & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lutz (US Pat#6183472). Lutz discloses a selective engagement mechanism (64,66) for an implant (14), a shaft (52) movable relative to the selective engagement mechanism, where the end surface of the hollow sleeve (42) is a second engagement surface that will which will rigidify the implant when it is retracted and the surface (42) is engaged with the head surface (18) of the implant via a distraction mechanism where surface (42) is pushing and tab portions (66,64) are pulling. The sleeve (42) of the shaft (52) is a rotatable collar surrounding the assembly and is coupled to the shaft by threads (54) such that rotation in one direction will extend the shaft arms (60, 62) and rotation in the other will retract them. The tabs (64, 66) of arms (60, 62) are retractable in a radial direction when the shaft retracts, where tabs will snap out of the recess, and move laterally apart, then retract back to the original shape after the screw is released, in an opposite fashion as described in column 3, lines 57-67.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Torrie (US Pat# 5667513). Torrie discloses a device fully capable of being a screw driver for a polyaxial screw where retractable fingers (23-26) are formed on the distal end that are fully capable of selectively engaging the head of a screw, where the end of the fingers are tabs (27) and may engage the shaft portion of a screw. The inner shaft (38) has surface (44), which is fully capable of engaging the shaft portion of a polyaxial screw and fixing it relative to the tabs, and is also capable of actuating the tabs to engage screw recesses. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Response to Arguments

Applicants' arguments filed April 11, 2006 have been fully considered but they are not persuasive.

Applicants argue that Becker does not teach an engagement mechanism for engaging a first part of an implant. However, Becker clearly teaches that the spindle (12), driver (19), and/or blade (20) engages the top of the screw, where the screw is an implant, such that the structure capable of performing the function of engaging is clearly present. The spindle, driver, and/or blade and claws of Becker clearly function to hold or rigidify the implant screw to the extent that this language can be given patentable weight. The fact that some modern implants are difficult to handle is not relevant to the present claims that have all the structural features of the claims.

Next, Applicants argue that Lutz does not disclose a selective engagement mechanism for engagement of an implant. However, the rejection clearly points out that elements (64) and (66) are the selective engagement mechanisms as claimed. Furthermore, the shaft (52) is clearly a shaft to the extent claimed. Additionally, the pedicle screw is clearly an implant to the extent that the term "implant" can be given patentable weight and it is only recited functionally or inferentially at best.

Allowable Subject Matter

Claims 11-14 are allowed over the prior art of record but not entirely for the reasons suggested by the Applicants. Rather, Becker lacks not only the retractable tabs but also the coupling pin extending from the inner shaft and interfering with the threaded inner surface of the collar to couple the inner shaft to the collar as claimed.

None of the prior art teaches this feature in a way that would make it obvious over Becker or any other prior art reference of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a long horizontal flourish extending to the right.

Paul Prebilic
Primary Examiner
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